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No. 03-83

IN THE

Supreme Court of the United States

CIGNA HEALTHCARE OF TEXAS, INC.,
Petitioner,

v.

RUBY R. CALAD, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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BRIEF OF THE COUNCIL OF STATE GOVERNMENTS, NATIONAL CONFERENCE OF STATE LEGISLATURES, NATIONAL ASSOCIATION OF COUNTIES, AND INTERNATIONAL CITY/COUNTY MANAGEMENT ASSOCIATION AS *AMICI CURIAE* SUPPORTING RESPONDENTS

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QUESTION PRESENTED

Whether § 502(a) of ERISA preempts negligent treatment claims filed under the Texas Health Care Liability Act.

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INTEREST OF THE *AMICI CURIAE*

Amici are organizations whose members include state, county, and municipal governments and officials throughout the United States.[1] *Amici* have a compelling interest in the issue in this case: whether ERISA preempts state laws regulating the medical treatment decisions of HMOs and Utilization Review Organizations (UROs).

The States have long protected the health and safety of their citizens by regulating the practice of medicine through both licensing requirements and tort liability. Under traditional systems of health care financing, insurers either paid or denied payment for completed medical procedures. Over the last thirty years, however, the provision of health care has become predominately subject to cost-control mechanisms such as utilization review. HMOs and UROs now routinely assert both the expertise and authority to override physicians' decisions as to the appropriate course of medical care while a patient's treatment is ongoing. These HMO and URO decisions can have a dramatic impact on patients' health with at times fatal results. States such as Texas have accordingly recognized the practical reality that utilization review frequently involves the practice of medicine, and that HMOs and UROs should be accountable for their negligent medical decisions.

CIGNA's broad reading of ERISA section 502(a) would create a regulatory void by rendering HMOs and UROs unaccountable for negligent treatment decisions. It would also impose on patients and their survivors the costs of injuries caused by the negligent treatment decisions of HMOs and

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[1] The parties have consented to the filing of *amicus* briefs in this case and have filed blanket consent letters with the Clerk of the Court. This brief was not authored in whole or in part by counsel for a party, and no person or entity, other than *amici* or their members, has made a monetary contribution to the preparation or submission of this brief.

UROs. Because such conduct is clearly outside the scope of ERISA, but squarely within the regulatory authority of the States, *amici* submit this brief to assist the Court in its resolution of this case.

SUMMARY OF ARGUMENT

1. The Court has repeatedly recognized the States' long-standing authority to protect the health and safety of their citizens by regulating health care. The Court has made clear that "in the field of health care, a subject of traditional state regulation, there is no ERISA preemption without clear manifestation of congressional purpose." *Pegram v. Herdrich*, 530 U.S. 211, 237 (2000). Thus, there is a strong presumption that ERISA does not preempt the Texas Health Care Liability Act (THCLA), Tex. Civ. Prac. & Rem. Code §§ 88.001-88.003.

Contrary to CIGNA's contention, ERISA section 502(a) does not overcome this presumption. Congress enacted the remedies of section 502 to address benefit denials under the then-predominate fee-for-service system. Under that system, insurers either paid or denied payment for completed medical procedures. Most significantly, utilization review organizations did not assert authority—as they do now—to override physicians' decisions as to the appropriate course of medical care while treatment was ongoing.

It is entirely appropriate for Texas to exercise its police powers to protect the health of its citizens by recognizing that utilization review decisions frequently involve the practice of medicine. The Texas act addresses the diffusion of authority for medical treatment decisions that has occurred with the widespread adoption of utilization review.

THCLA imposes liability on an HMO only for failing "to exercise ordinary care when making health care treatment decisions." Tex. Civ. Prac. & Rem. Code § 88.002(a). The Act does not impose any obligation on an HMO "to provide . . . treatment which is not covered by the health

care plan." *Id.* § 88.002(d). Calad's THCLA claim does not present a dispute over the terms of the plan. Her claim is not for "improper processing of a claim for benefits," *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 57 (1987), but rather for the independent tort which occurred when (as she alleges) CIGNA overrode her treating physician's decision, substituted its own judgment as to the course of necessary medical treatment, and caused her injury.

Neither ERISA nor DOL's regulations impose any substantive standard of conduct applicable to HMOs and UROs in making treatment decisions. *See Pegram*, 530 U.S. at 232-37. CIGNA's position would thus create a regulatory void with the perverse result that those patients who defer to an HMO's supposed medical expertise and do not challenge its treatment decision are remediless when that decision causes them injury. The Court should reject CIGNA's attempt to transfer accountability for, and the costs of, its negligent medical decisions onto its patients. Such a result is irreconcilable with ERISA's policy "to protect the interests of participants in employee benefit plans and their beneficiaries." 29 U.S.C. § 1001(b).

2. None of CIGNA's policy arguments support extending ERISA preemption to immunize HMOs and UROs from liability for their negligent treatment decisions. Contrary to CIGNA's assertion, ERISA section 502(a)'s remedies of a suit for reimbursement or a suit for injunctive relief are not always effective. Most patients typically do not have the financial means to pay for a procedure in advance. Indeed, that is why they join their employer's health plan. Similarly, whether a particular medical treatment is medically necessary is a highly complex and fact-intensive issue. Thus, the costs of litigating a suit for injunctive relief are likely to be substantial. Just as most people lack the financial resources to pay for treatment in advance, they also cannot underwrite a suit for injunctive relief. Moreover, while under ERISA, the

court, "in its discretion may" award attorney's fees "to either party," 29 U.S.C. § 1132(g)(1), few attorneys will undertake such a costly and time-consuming litigation given that if they do not prevail, they will receive no compensation for their time and expenses. Finally, ERISA's remedies are totally inadequate where a patient defers to the HMO/URO's decision regarding appropriate treatment and subsequently suffers injury.

Finally, CIGNA and its *amici* refute their own contention that subjecting HMOs and UROs to tort liability for their negligent treatment decisions "will vastly increase the costs of providing benefits" and result in a reduction in health care coverage for workers. CIGNA Br. 48. As CIGNA and its *amici* acknowledge, only a very small percentage of claim denials involve the issue of whether treatment was medically necessary. Beyond the fact that the number of potential lawsuit-triggering decisions is low, not every wrongful denial of medically necessary treatment will result in a lawsuit. Notwithstanding an HMO/URO's negligent treatment decision, a patient may not suffer an injury and even those who are injured will not necessarily sue. Finally, the litigation experience of several large non-ERISA plans suggests that such lawsuits will have only a minimal impact on plans' costs.

ARGUMENT

ERISA SECTION 502(a) DOES NOT PREEMPT NEGLIGENT TREATMENT CLAIMS FILED UNDER THE TEXAS HEALTH CARE LIABILITY ACT

The court of appeals properly rejected CIGNA's contention that ERISA section 502(a), 29 U.S.C. § 1132(a), completely preempts claims brought under the Texas Health Care Liability Act (THCLA), Tex. Civ. Prac. & Rem. Code §§ 88.001—88.003 (reproduced in CIGNA Pet. App. 56a-63a). As this Court has recognized, health insurers—whether health maintenance organizations (HMOs), managed care

organizations (MCOs), or utilization review organization (UROs)—frequently do far more than make simple benefit eligibility determinations. *See Pegram v. Herdrich*, 530 U.S. 211, 228-29 (2000).

"[A] great many and *possibly most* coverage questions are not simple yes-or-no questions, like whether appendicitis is a covered condition. . . ." *Id.* at 228 (emphasis added). Rather, they involve the "when-and-how question" of "whether one treatment option is so superior to another under the circumstances, and needed so promptly, that a decision to proceed with it would meet the medical necessity requirement that conditions the HMO's obligation to provide or pay for that particular procedure at that time in that case." *Id.* at 229. In short, they are medical judgments which are well beyond the scope of Congress's regulatory purpose in enacting ERISA. *See id.* at 236 ("ERISA was not enacted . . . in order to federalize malpractice litigation").

As explained below, Texas's creation of a statutory cause of action for persons injured by a medical insurer's negligence in overriding a physician's judgment as to the required course of treatment and prescribing different and inadequate treatment, is not a suit "to recover benefits" or "to enforce [one's] rights under the terms of [a] plan." 29 U.S.C. § 1132(a)(1)(B). Such a suit does not challenge an ERISA administrator's interpretation of the plan, but rather its medical judgment regarding the course of required treatment.

Because this case involves an exercise of the State's historic powers to regulate the practice of medicine and the insurance industry, ERISA no more preempts Calad's state-law claims than it does state regulations requiring that HMOs and MCOs employ properly credentialed physicians and nurses in providing health care. *Cf. De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806 (1997). Indeed, adoption of CIGNA's position would create the perverse result that HMOs, MCOs, UROs, and insurers are immunized

from damages liability for injuries caused by their negligence in making medical decisions in administering an ERISA medical plan, but not when they administer employee benefit plans that are not subject to ERISA, *see* 29 U.S.C. § 1003(b), or when they administer a health insurance contract generally. The judgment of the court of appeals should therefore be affirmed.

A. Neither Section 502(a) Nor ERISA's Statutory Purpose Manifest Congress's Intent To Preempt State-Created Causes Of Action Against HMOs, MCOs, and UROs For Failing To Exercise Ordinary Care In Making Health Care Treatment Decisions

The Court has repeatedly held that "the historic police powers of the State include the regulation of matters of health and safety." *De Buono*, 520 U.S. at 814 (citing *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985)). *See also Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 387 (2002) (upholding state independent review statute against ERISA preemption challenge). Moreover, the Court has further recognized that a State can "regulate insurance as one way to regulate the practice of medicine" and that such regulation is "permissible under ERISA." *Id.* (citing *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 741 (1985)). Indeed, the Court has explained "that regulating insurance tied to what is medically necessary is probably inseparable from enforcing the quintessentially state-law standards of reasonable medical care." *Id.* (citing *Pegram*, 530 U.S. at 236).

This Court has thus made clear that "in the field of health care, a subject of traditional state regulation, there is no ERISA preemption without clear manifestation of congressional purpose." *Pegram*, 530 U.S. at 237. CIGNA thus "bear[s] the considerable burden of overcoming 'the starting presumption that Congress does not intend to supplant state

law.'" *De Buono*, 520 U.S. at 814 (quoting *New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654 (1995)). That burden is even greater where, as here, a state law also regulates the practices of insurers, *see* Tex. Civ. Prac. & Rem. Code § 88.002, an area which ERISA expressly saves from preemption. *See* 29 U.S.C. § 1144(b)(2)(A) ("nothing in [ERISA] shall be construed to exempt or relieve any person from any law of any State which regulates insurance"); *Kentucky Ass'n of Health Plans, Inc. v. Miller*, 538 U.S. 329 (2003).

CIGNA nonetheless argues that Section 502(a), ERISA's civil enforcement provision, completely preempts Calad's claim under THCLA because it provides the exclusive remedial scheme for the participants and beneficiaries of ERISA plans to challenge benefit denials. *See* CIGNA Br. 11-15 (citing *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41 (1987)). *See Pilot Life*, 481 U.S. at 52 (holding that section 502 is "the exclusive vehicle for actions by ERISA-plan participants and beneficiaries asserting the improper processing of a claim for benefits")). According to CIGNA, "[t]he real question is whether [Calad's] THCLA claim seeks to remediate the violation of a right already protected by ERISA." CIGNA Br. 24.

Most troubling, CIGNA asserts that the "the injuries [Calad] seeks to remedy follow only from the fact that CIGNA, she says, improperly refused to cover the expenses of the additional time in the hospital." *Id.* According to CIGNA, because "[i]t is undeniable that Calad could have brought a § 502(a)(1)(B) action to obtain exactly what her THCLA claim asserts was wrongfully denied her—the payment of the expenses of the additional hospital stay," her claim "seeks additional remedies for an assertedly improper denial of her hospital stay benefit, [and] is completely preempted under *Pilot Life*." *Id.* at 24-25.

The Court should reject CIGNA's attempt to immunize itself from accountability when it overrides a treating physician's judgment and substitutes it own negligently made medical decision as to the appropriate course of a patient's medical care. True enough, some claims that arise out of benefit disputes—such as the refusal to pay a submitted claim or authorize a procedure in advance—are properly deemed to be within the scope of section 502(a)(1)(B). But many disputes between patients or survivors and HMOs/UROs are not susceptible to resolution under section 502(a)(1)(B), especially where, as here, HMOs and UROs assert the medical expertise and authority to make medical treatment decisions. Because ERISA provides no substantive standard applicable to medical treatment decisions, *Pilot Life*, which holds only that a state law claim "asserting improper processing of a claim for benefits" is preempted, 481 U.S. at 52, is not controlling.

As a general matter, CIGNA's approach creates the paradoxical result that patients such as Calad who accept an HMO's judgment as to the course of appropriate treatment are left utterly remediless for the injuries they suffer when that judgment turns out to have been negligently made. Moreover, CIGNA's view takes no account of the reality that most patients lack the requisite knowledge and training in medicine to challenge an HMO's determination of medical necessity. As CIGNA's *amici* acknowledge, "[a]t a moment of need an insured patient, while the ultimate 'consumer' of the care, typically lacks . . . the expertise to make informed decisions for himself." Br. *Am. Cur.* AAHP-HIAA *et al.* 9. Yet under CIGNA's view, these same patients are denied any remedy for their injury when they rely on their HMO's judgment that a particular course of treatment is not medically necessary, while HMOs, MCOs and UROs, which assert the expertise to override the judgments of treating physicians, are shielded from liability for the harm caused by their negligent medical decisions.

The foregoing acknowledgement of CIGNA's *amici* is especially relevant to Calad's case. As anyone who has undergone major surgery knows, following the procedure a patient is prescribed pain medication that affects their decision-making ability. Indeed, discharge instructions commonly advise the patient against making any important business or legal decisions following surgery. *See, e.g.*, Veterans Administration Medical Center, Houston, Texas, *Outpatient Surgery Handbook—Discharge Planning*, available at http://www.houston.med.va.gov/handbooks/op_surgery/recovery.html (visited Jan. 19, 2004) ("you should not . . . make important decisions until at least one day following surgery or longer"); Temple University Hospital, *Patient Information—Information for Day Surgery Patients*, available at http://www.health.temple.edu/tuh/General_Information/day_of_procedure.html (visited January 7, 2004) ("You should not . . . make any legal decisions for 24-48 hours following your discharge."). A patient is thus typically in no condition to evaluate the correctness of a benefits denial that results in a discharge and to determine whether to pursue an immediate administrative appeal of a denial of a longer hospital stay.[2] Nor for that matter is a patient then capable of

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[2] CIGNA argues that Calad had available several remedies to appeal CIGNA's discharge order. *See* CIGNA Br. 42-44. CIGNA emphasizes Calad's failure to invoke these remedies upon being informed by CIGNA in pre-authorization that absent certain symptoms she was entitled to only a one-day stay in the hospital under its discharge protocol. *See id.* at 43-44.

These arguments are unpersuasive for several reasons. First, surgery is an extremely stressful event for the patient. Prior to surgery, most patients are under too much stress to do battle with their HMO. Second, a patient has no basis for knowing before the procedure whether they will have post-operative symptoms warranting a longer stay.

Moreover, following a major procedure a patient is in no condition to make a reasoned decision as to whether to challenge a discharge determination. Nor, even assuming that Calad was in sufficient condition to challenge the discharge, is it clear that an appeal of CIGNA's discharge

making a rational decision as to whether to stay in the hospital, pay for the additional days out of their own pocket, and later bring a suit for reimbursement under section 502(a)(1)(B).[3] *See* Pet. Br. 43. Again under CIGNA's view, that patient is barred from any remedy when CIGNA has overridden a physician's judgment as to the course of appropriate treatment and thereby caused injury to the patient.

CIGNA's argument is undercut by the fact that Congress enacted the remedies of section 502 in 1973 to address benefit denials under the then-predominate "fee-for-service" system. *Cf. Pegram*, 530 U.S. at 218. Under that system, insurers

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determination could have been adjudicated in a timely fashion prior to her discharge. *See* CIGNA Br. 42-43 (discussing DOL regulations which were not in existence at time of Calad's procedure).

[3] That DOL's regulations require a plan to allow the patient's physician to represent the patient in an appeal of an adverse benefits determination, *see* 29 C.F.R. § 2560.503-1(b)(4), does not support a contrary conclusion. It is unclear whether a physician has a legal "'duty to advocate' with a patient's health care plan when it denies or delays treatment the physician has requested." *Pryzbowski v. U.S. Healthcare, Inc.*, 245 F.3d 266, 281 (3d Cir. 2001). In *Pryzbowski*, the Medical Society of New Jersey filed an *amicus* brief arguing that physicians have no such duty, and the court of appeals expressly noted "that physicians, under existing New Jersey law, have no duty to advocate on behalf of their patients to an HMO or any health insurance plan for the timely approval of benefits." *Id.* at 282.

Nor given the workload of physicians, and the view of some physicians that certain insurance companies systematically and unreasonably deny claims, is it surprising that physicians would oppose the creation of any such obligation. *Cf.* Tom Graham, *Docs Feel Hassled, Too*, Washington Post, Dec. 23, 2003, at HE2 (noting that "'less than honorable patterns of paying claims' . . . recently led insurance giants Aetna and Cigna to settle federal class actions suits filed by doctors"); Dan Christensen, *In Doctors' National HMO Suits, Aetna and Cigna Decide To Settle*, Palm Beach Daily Bus. Rev., Dec. 15, 2003, at 10 (noting doctors' allegation that "under the banner of cost containment, . . . Aetna, . . . Cigna and other managed care companies conspired to cheat them out of billions of dollars by denying or manipulating claims to wrongly reduce or delay payments").

either paid or denied payment for completed medical procedures. And utilization review organizations did not assert authority—as they do now—to override physicians' decisions as to the appropriate course of medical care while treatment was ongoing. *Cf.* Jonathan J. Frankel, Note, *Medical Malpractice Law and Health Care Cost Containment: Lessons for Reformers from the Clash of Cultures*, 103 Yale L.J. 1297, 1303 (1994); *see also* Jeffrey E. Shuren, *Legal Accountability for Utilization Review in ERISA Health Plans*, 77 N.C. L. Rev. 731, 742 (1999) ("Between 1982 and 1985, twenty-seven percent of U.S. companies introduced utilization review into their health plans. . . . In 1996, approximately ninety percent of employers used some type of utilization review in their health plans.").

Contrary to CIGNA's views, it is entirely appropriate for Texas to exercise its police powers to protect the health of its citizens by recognizing that utilization review decisions frequently involve the practice of medicine. Texas has acted to address the diffusion of authority for medical treatment decisions that has occurred with the wide-spread adoption of utilization review systems. As one commentator explains:

> Although third-party payers claim that their decisions are benefits determinations and not medical decisions, the effect of their decisions is to determine what treatment a patient should receive. Because most patients cannot afford treatment without reimbursement from the plan and most physicians cannot afford to provide care without reimbursement, a determination that treatment is not appropriate and, therefore, will not be paid for by the plan, is in effect a decision not to provide care or to provide alternative care. A UR decision is, therefore, akin to and frequently has the effect of a medical decision by a treating physician. This similarity is highlighted by the fact that UROs use health care providers, such as physicians and nurses, to make UR determinations and to design UR guidelines.
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> * * *

> Not only are UROs interposing themselves into medical decisionmaking by determining what is medically necessary, they are also changing the physician standard of care by affecting physician decisionmaking and, therefore, physician practice. UROs evaluate a treating physician's plan of care using their own medical experts. Moreover, they "recommend" alternative courses of treatment with the knowledge that most patients will follow their directions. The arrangements between third-party payers, UROs, and physicians, therefore, distribute medical authority among several actors.

Shuren, *supra*, at 747-48.[4]

It is true, as the Court recognized in *Pegram*, that many utilization review decisions do not involve the practice of medicine and are thus properly characterized as simple benefits determinations. *See* 530 U.S. at 228-29. But as *Pegram* further recognized, some UR decisions clearly do involve the practice of medicine. This is amply demonstrated in various cases where HMOs and UROs have overridden the treating physician's diagnosis and plan of care and substituted their own opinion of what constitutes necessary medical treatment in a given case. *See id.* at 229.

For example, in *Land v. CIGNA Healthcare of Fla.*, 339 F.3d 1286 (11th Cir.), *petition for cert. filed*, No. 03-649 (Oct. 28, 2003), the treating physicians diagnosed a CIGNA HMO member as having a serious non-localized infection, which required hospitalization "for aggressive intravenous

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[4]Another authority likewise explains:

> [T]hird party payors, in the context of managed-care arrangements, often make decisions that we would normally consider to be medical ones. Utilization review companies evaluate a treating physician's plan of care using their *independent medical expertise*; in addition, they suggest alternative courses of treatment with the knowledge and expectation that most patients will follow their prescriptions.

Frankel, *supra*, at 1320 (emphasis added).

antibiotic treatment and constant monitoring and assessment of his infection to determine whether surgery or modified antibiotic treatment would be necessary." *Id.* at 1288. Shortly after the patient was admitted, a CIGNA approval nurse reviewed the treating physicians' plan of care. *See id.* While the CIGNA nurse agreed with the physicians' prescription of intravenous antibiotic therapy, she reached a contrary conclusion as to treatment, deciding that Land had "a localized infection that did not require hospitalization." *Id.* She therefore disapproved Land's hospitalization and he was discharged. *See id.* Following his discharge, Land's condition deteriorated; he subsequently underwent multiple surgeries and ultimately had his index finger amputated. *See id.* at 1288-89.

In CIGNA's view, its reviewing nurse's action was merely a determination of Land's benefits under his health insurance plan. *See id.* at 1290. According to CIGNA, Land has no remedy against it notwithstanding that its reviewing nurse clearly made a medical error when she substituted her own diagnosis of a localized infection for the treating physicians' conclusion that Land had a more serious infection that required inpatient monitoring.

Likewise, in *Roark v. Humana, Inc.*, a patient required continued use of a vacuum-assisted closure device (VAC) and daily home nursing care to treat a leg wound. *See* 307 F.3d 298, 303 (5th Cir. 2002). Notwithstanding that the patient's primary care physician had informed the HMO "that without the VAC and home nursing care, Roark could lose her leg," the HMO "periodically delayed VAC and home nursing treatment" and eventually "cancelled home nursing altogether." *Id.*[5]

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[5] According to the Fifth Circuit, Roark had repeatedly challenged the HMO's attempts to terminate VAC treatment and home nursing care. *Id.* at 303. Her pursuit of these remedies did not deter the HMO from its determination to terminate medically necessary treatment.

Within three months, Roark "developed a serious infection" that resulted in the amputation of her leg. *Id.* at 303-04. Following the procedure, the HMO "again denied [Roark] VAC treatment that may have helped heal the amputation wound." *Id.* at 304. Less than a year later, Roark was forced to undergo "an additional amputation treatment on her leg." *Id.*

Again, under CIGNA's view, Congress has immunized the HMO from liability in Roark's case notwithstanding the serious injury she incurred as a result of its decision to override the medical treatment prescribed by her treating physician. And again, the HMO is unaccountable for its medical decision notwithstanding that it asserted both expertise and authority to override a treating physician's prescription of a course of medically necessary treatment.

Similarly, in *Isaac v. Seabury & Smith, Inc.*, 2002 WL 1461710 (S.D. Ind. 2002), a patient being treated at the M.D. Anderson Cancer Center, one of the nation's leading cancer facilities, was diagnosed by her oncologist as having chronic myelogenous leukemia. The oncologist contacted the URO seeking "Urgent Review" of the patient's need for a bone marrow transplant. *Id.* at *1. In his written diagnosis, the oncologist stated that the patient's condition was "unstable." *Id.* The oncologist further concluded that neither chemotherapy nor radiation was likely to cure the patient's illness and that "'[t]he only documented therapy capable of curing this disease is bone marrow transplantation from a histocompatible donor.'" *Id.* (citation omitted).

Nonetheless, the URO denied coverage on the ground that the prescribed procedure was not "medically necessary." *Id.* Although four weeks later the URO modified the denial and gave "conditional approval" for the procedure, *id.* at 2, the patient died two weeks later before the transplant could be performed. *See id.*

CIGNA's position is that an ERISA plan patient should, upon being denied necessary treatment, pursue an administrative appeal and, if it is denied, "arrange to pay for the procedure outside the plan, and then file a § 502(a)(1)(B) action seeking reimbursement for the expenses." CIGNA Br. 43. Alternatively, CIGNA maintains that the patient can sue under § 502 for an injunction to enforce plan terms. *See id.* at 27-31, 42-44. For most patients, neither choice provides an effective remedy.

Few patients have the financial means to pay for a bone marrow transplant or the treatments necessary to cure other serious illnesses and conditions. Indeed, that is why people purchase health insurance or join their employer's health plan in the first place.

Nor, in most cases, does a suit for an injunction provide a realistic remedy. Given the "highly fact-intensive" nature of the issues, with the likely need for expert testimony on what care is medically necessary and complies with the prevailing standard of care, "[t]he costs of such suits are likely to be immense." *DiFelice v. Aetna U.S. Healthcare*, 346 F.3d 442, 459, 458 (3d Cir. 2003) (Becker, J., concurring). While under ERISA "the court in its discretion may allow a reasonable attorney's fee and costs of action to either party," *see* 29 U.S.C. § 1132(g)(1), it does so "if at all, only after the action concludes." *DiFelice*, 346 F.3d at 458 (Becker, J., concurring). Just as most people lack the financial resources to pay for treatment in advance, they also cannot underwrite a suit for injunctive relief. And few attorneys will undertake such costly and time-consuming litigation given that if they do not prevail, they will receive no compensation for their time and expenses. Thus, in most instances involving treatment decisions, section 502's remedies are, as Judge Becker concluded, "entirely illusory." *Id.* at 459 (Becker, J., concurring).

CIGNA's contention is thus simply an attempt to transfer accountability for, and the costs caused by, its negligent medical decisionmaking from itself onto its patients. Acceptance of this view would lead to the perverse result that those patients who defer to an HMO's supposed medical expertise and do not challenge the HMO's decision regarding appropriate treatment—that is, "most patients," Shuren, *supra*, at 748—are left without a remedy when that decision causes them injury. The Court should reject this inequitable contention, which is totally contrary to ERISA's core purpose of protecting "the interest of employees and their beneficiaries in employee benefit plans." *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 90 (1983).

Indeed, the Court has frequently dismissed similar assertions that federal law preempts state law where, as here, doing so would result in the denial of any effective remedy. The Court has rejected the proposition "that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984); *cf. Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487 (1996) (rejecting preemption claim that would "have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation" to protect health and safety).

To similar effect is *United Constr. Workers v. Laburnum Constr. Corp.*, 347 U.S. 656 (1954). There the Court dismissed the contention that federal law preempted a state tort action based on conduct that also constituted an unfair labor practice under the LMRA, 29 U.S.C. § 187. While acknowledging that Congress had authorized preventive relief against unfair labor practices, as well as a limited damages remedy for illegal secondary boycotts, the Court declined to hold state tort actions preempted. It reasoned that "[t]o do so will, in

effect, grant petitioners immunity from liability for their tortious conduct." 347 U.S. at 664.

The Court explained that "[t]o the extent that Congress prescribed preventive procedure against unfair labor practices . . . the [LMRA] excluded conflicting state procedure to the same end." *Id.* at 665. The Court held, however, that "[t]o the extent . . . Congress has not prescribed procedure for dealing with the consequences of tortious conduct already committed, there is no ground for concluding that existing criminal penalties or liabilities for tortious conduct have been eliminated." *Id.* The Court concluded that to hold state law preempted would "mean that where the federal preventive . . . procedures are impotent or inadequate, the offenders, by coercion of the type found here, may destroy property without liability for the damage done." *Id.* at 669.

The Court's LMRA jurisprudence is particularly instructive given that "§ 502(a) [of ERISA] was modeled on the exclusive remedy provided by § 301 of the [LMRA]." *Pilot Life*, 481 U.S. at 52. Although *United Construction Workers* did not involve § 301, "even under § 301 [the Court has] never intimated that any action merely relating to a contract within the coverage of § 301 arises exclusively under that section." *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 25 n.28 (1983). As the Court further stated, "a state battery suit growing out of a violent strike would not arise under § 301 simply because the strike may have been a violation of an employer-union contract." *Id.* (citation omitted).

Rather, what section 301 preempts is a "state-law claim [whose resolution] is *substantially dependent* upon the analysis of the terms of an agreement made between the parties in a labor contract." *Allis-Chalmers Corp. v. Lueck*, 471 U.S. 202, 220 (1985) (quoted in *Pilot Life*, 481 U.S. at 55) (emphasis added). But like a battery claim that arises in the context of a labor dispute, Calad's claim for negligent

medical treatment is not "substantially dependent upon the analysis of the terms" of her health care benefit plan.

THCLA imposes liability only for failing "to exercise ordinary care when making health care treatment decisions." Tex. Civ. Prac. & Rem. Code § 88.002(a). The statute defines a "health care treatment decision" in relevant part as "a decision which affects the quality of the diagnosis, care, or treatment provided to the plan's insureds or enrollees." *Id.* § 88.001(5). Furthermore, the statute expressly states that it "create[s] no obligation on the part of the . . . [HMO] to provide to an insured or enrolled treatment which is not covered by the health care plan of the entity." *Id.* § 88.002(d).

Calad's THCLA claim does not present a dispute over the terms of the plan. She was entitled to remain in the hospital as long as the stay was medically necessary. *See* CIGNA Br. 3. The underlying dispute is whether, in light of Calad's post-operative condition, CIGNA's decision that she be discharged one day after major surgery complied with the "duty to exercise ordinary care" as defined by "the prevailing practices and standards of the medical profession and community." Tex. Civ. Prac. & Rem. Code §§ 88.002(a); 88.001(1). Her claim is not one for the "improper processing of a claim for benefits," *Pilot Life*, 481 U.S. at 52, but rather for the independent tort which occurred when (as she alleges) CIGNA overrode her treating physician's decision, substituted its own judgment as to the course of necessary medical treatment, and caused her injury.

Neither ERISA nor DOL's regulations impose any substantive standard of conduct applicable to HMOs and UROs in making treatment decisions. *See Pegram*, 530 U.S. at 232, 236; 29 C.F.R. § 2560.503-1. It is thus implausible to suggest that ERISA section 502 should be construed to completely preempt Calad's claim and thereby create a regulatory void. Indeed, acceptance of CIGNA's contention would "have the perverse effect of granting complete immunity" from mal-

practice liability when a patient's health care is provided by an ERISA plan but not when a patient's care is provided by a plan that is not subject to the statute. *See Medtronic*, 518 U.S. at 487. Given ERISA's purpose of protecting plan participants and beneficiaries, *see* 29 U.S.C. § 1001(b), it would be an especially problematic to leave ERISA plan members who have been injured by the negligent treatment decisions of HMOs and UROs worse off than persons covered by non-ERISA plans. As there is no evidence that this was Congress' intent, the Court should reject CIGNA's preemption argument.

B. CIGNA's Policy Arguments Are Unpersuasive And Do Not Justify Immunizing HMOs, MCOs and UROs From Liability For Negligently Made Medical Decisions

In their effort to extend ERISA preemption to immunize themselves from the consequences of negligent medical decisions, CIGNA and its *amici* make several policy arguments. *See* CIGNA. Br. 42-49; Br. *Am. Cur.* AAHP-HIAA at 19-26. To believe CIGNA and its *amici*, allowing patients to bring tort suits against HMOs and UROs would have dire consequences for the employer-based system of health care. As explained below, these contentions do not withstand scrutiny. Moreover, they are patently insufficient to justify "insulat[ing] HMOs from liability for even the most egregious acts of dereliction committed against plan beneficiaries." *DiFelice,* 346 F.3d at 453 (Becker, J., concurring).

First, CIGNA contends that ERISA already "provides numerous protections for ERISA plan beneficiaries' rights." CIGNA Br. 42. But as explained at pp. 15-16, *supra*, those remedies are not always meaningful.[6] Most signifi-

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[6] *Nguyen v. Healthguard of Lancaster, Inc.*, 282 F. Supp.2d 296 (E.D. Pa. 2003), demonstrates the erroneousness of petitioner's regime. There, a URO rejected the recommendations of four different physicians that

cantly, those remedies are totally inadequate where a patient defers to the HMO/URO's decision regarding appropriate treatment and subsequently suffers injury. It is perverse to transfer the costs of negligent treatment decisions from entities that assert the expertise to override medical judgments onto patients who typically lack such expertise. *See* Br. *Am. Cur.* AAHP-HIAA at 9 ("an insured patient . . . typically lacks . . . the expertise to make informed decisions for himself").

Moreover, adoption of CIGNA's position would "create[] a monetary incentive for HMOs to mistreat . . . beneficiaries, who are often in the throes of medical crises and entirely unable to assert what meager rights they possess." *DiFelice*, 346 F.3d at 453-54 (Becker, J., concurring). Under CIGNA's proposed scheme, "if an HMO wrongly denies a participant's claim even in bad faith, the greatest cost it could face is being compelled to cover the procedure, the very cost it would have faced had it acted in good faith." *Id.* at 459. As Judge Becker has further explained, "[a]ny rational HMO will recognize that if it acts in good faith, it will pay for far more procedures than if it acts otherwise, and punitive damages, which might otherwise guard against such profiteering, are no obstacle at all." *Id.*[7] Indeed, not even the prospect of paying

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Nguyen needed a particular procedure. *Id.* at 299-300. While Nguyen pursued several administrative appeals, the URO repeatedly failed to forward to the reviewer critical evidence (CT scan films) which supported Nguyen's need for the procedure. *See id.* at 300-01. While ultimately, Nguyen was forced to bring a section 502 claim, the insurer's bad faith rendered the administrative appeals meaningless.

[7] Contrary to CIGNA's assertion, *see* CIGNA Br. 44-46, the fact that in some instances (such as a self-funded plan) an HMO/URO does not bear the financial risk of treatment costs does not justify immunizing them from liability for negligent treatment decisions. Even under these arrangements the HMO/URO may have a financial incentive to deny treatment as the HMO/URO's performance of its contract may be judged by whether it has held the line on costs. In any event, CIGNA's market

compensatory damages exists to deter HMOs and UROs from the negligent making of treatment decisions. *See id.*

CIGNA further asserts that "imposing the medical malpractice tort regimes of the various states on employee health benefit coverage decisions will vastly increase the costs of providing benefits." CIGNA Br. 48. Putting aside that liability under THCLA attaches only to treatment decisions, *see supra* p. 18, the litigation experience of non-ERISA plans amply refutes this contention.

In the late 1990s, the Henry J. Kaiser Family Foundation[8] commissioned a study of three large non-ERISA health care plans: those of the California Public Employees Retirement System (CalPERS), Los Angeles Unified School District (LAUSD), and State of Colorado Employee Benefit Plan.[9] It found that "[a]ll three programs reported very low rates of litigation ranging from 0.3 to 1.4 cases per 100,000 enrollees per year." Coopers & Lybrand, L.L.P., *Impact of Potential Changes to ERISA: Litigation and Appeal Experience of CalPERS, Other Large Public Employers and a Large California Health Plan* 5 (Henry J. Kaiser Family Foundation 1998). Based on an assumed "average cost per case for litigation of $100,000" and CalPERS's estimated cost of $10,000 for an administrative hearing, the study found that "the direct monthly cost per enrollee related to litigation ranged between $0.03 and of $0.13." *Id.* at 6.

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incentives approach does not justify imposing on patients the costs of injury caused by an HMO/URO's negligent treatment decisions.

[8] The Henry J. Kaiser Family Foundation is a non-profit private foundation that studies health care issues.

[9] At the time of the study, CalPERS had about one million members in its health care plan; the LAUSD had 70,000 members, and Colorado had 30,000. *Impact of Potential Changes to ERISA*, *supra*, at 2. Eighty percent of CalPERS's and Colorado's health plan members were enrolled in managed care; one hundred percent of LAUSD's members were enrolled in HMOs or HMO point of service plans. *See id.*

The Kaiser Study also examined the litigation rate of a large California insurer/HMO before and after the Court's *Pilot Life* decision. *See Impact of Potential Changes to ERISA*, *supra*, at 6-7. Before *Pilot Life*, the insurer/HMO had a litigation rate of 3.2 cases per 100,000 enrollees; after *Pilot Life*, the litigation rate was 2.4 cases. *Id.* These figures, however, included "both group and individual coverage cases," the latter not being subject to ERISA. *Id.* at 7. The study further determined that even at the higher litigation rate, and assuming a $100,000 average cost per claim, the litigation cost would only be "$0.27 per person per month." *Id.* at 8. Thus, contrary to the predictions of CIGNA and its *amici*, subjecting HMOs and UROs to liability is not likely to have more than a minimal effect on the costs of ERISA plans.

Indeed, CIGNA and its *amici* refute their own prediction of "vastly increase[d] . . . cost[s]." CIGNA Br. 48. As *amici* AAHP-HIAA acknowledge, "there is no reason to think that there is a widespread problem of plan participants wrongly denied coverage for necessary care, and then subjected to bad medical outcomes . . . . MCOs deny only a small percentage of coverage claims, and only a few of those denials are based on a failure to meet pre-authorization criteria." Br. *Am. Cur.* AAHP-HIAA 22; *see also id.* at 22 n.47 ("Of the less than 2% of plan enrollees who are initially denied coverage, only 6% of denials resulted from failure to meet pre-authorization criteria") (citation omitted); CIGNA Br. 46 (asserting that the percentage of "claims denied because they are not medically necessary represent" is less than "2.8 percent of the total claims submitted").

Whether or not these "numbers . . . support assertions that HMOs pursue profits by denying claims without attention to their merit," CIGNA Br. 46,[10] they clearly do not support

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[10] This contention cannot, of course, be evaluated without knowing the nature and costs of the treatments being denied. *See, e.g., Cicio v. Does*, 321 F.3d 83, 88 (2d Cir.) (denying approval of double stem cell transplant

CIGNA's contention that allowing ERISA participants and beneficiaries to sue HMOs and UROs for negligent treatment decisions "will vastly increase the costs of providing benefits, all but guaranteeing" less health care for workers. *Id.* at 48. Beyond the fact that the number of potential lawsuit-triggering decisions is low, not every wrongful denial of medically necessary treatment will give rise to a lawsuit. Notwithstanding the HMO/URO's negligent treatment decision, a patient may not suffer an injury. And those who suffer injury because of an HMO's or URO's tortious treatment will not necessarily sue. [11] In short, even when state law remedies such as THCLA are available, the number of lawsuits is likely to be low and, as the Kaiser Study

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for patient with multiple myeloma), *petition for cert. filed*, No. 03-69 (July 11, 2003); *Isaac*, 2002 WL 1461710, at *1-2 (denying approval of bone marrow transplant for patient with myelogenous leukemia). Undoubtedly, many of the denials involve the most costly treatments.

[11] There is substantial evidence that many patients injured by medical malpractice do not sue. *See* Carole Roan Gresenz, *et al.*, *A Flood of Litigation? Predicting the Consequences of Changing Legal Remedies Available to ERISA Beneficiaries* 5 (1999), available at http://www.rand.org/publications/IP/IP184/index.html. According to the Harvard Medical Practice Study, "very few (approximately 3 percent) of the patients whom physician reviewers deemed to be victims of negligence in the course of their hospitalizations brought malpractice claims." *Id.* (citing Harvard Medical Practice Study, *Patients, Doctors, and Lawyers: Medical Injury, Malpractice Litigation, and Patient Compensation in New York* (1990)).

While "many of the patients [in the Harvard study] . . . fully recovered from the injury within six months," *id.*, another study "found that only 33 percent of patients who were *seriously injured* by negligent care filed medical malpractice claims." *Id.* (emphasis added) (citing D. M. Studdert, *et al.*, *Suing for Medical Malpractice in Utah and Colorado in 1992* (unpublished manuscript)). Furthermore, because medical malpractice litigation is typically conducted on a contingency fee basis, "medical malpractice plaintiff attorneys are highly selective in deciding what claimants to represent because of the high costs of this specialized litigation and the risk of not obtaining compensation." *Id.*

indicates, such lawsuits will have only a minimal effect on the cost of health care.

CIGNA acknowledges that utilization review systems "have not been perfected . . . and may never be." *Id.* at 47. Indeed, as long as the only liability an HMO faces if it makes an erroneous treatment decision is the cost of the care it should have provided, it will have little incentive to improve its UR systems to reduce erroneous decisions. Moreover, where a URO does not bear the cost of care, under CIGNA's theory, it will have no incentive to improve its systems. Finally, whether utilization review systems produce better health care outcomes overall than do other methods of health care delivery and financing, *see id.*, that does not justify pre-empting state law remedies and allowing HMOs and UROs to shift the costs of their negligent medical treatment decisions onto patients.

ERISA does not provide a substantive standard applicable to HMO and URO medical treatment decisions. *See Pegram*, 530 U.S. at 236. Such regulation is, however, squarely within the realm of the States' longstanding authority to protect their citizens' health and safety. *See id.* at 237. The Court should therefore reject CIGNA's contention that ERISA preempts Calad's state-law medical negligence claim.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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